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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,056	01/11/2001	Diane Pennica	GENENT.2827A2	1938

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EXAMINER
BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/06/2002 17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,056	Applicant(s) Pennica et al
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Aug 12, 2002* .

2a) This action is **FINAL**. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-95* is/are pending in the application.

4a) Of the above, claim(s) *5, 6, 12-14, 17, and 22-95* is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) X Claim(s) *1, 2, 4, 7-11, 15, 16, and 18-21* is/are rejected.

7) X Claim(s) *3* is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

1 X Notice of References Cited, PTO-892
2 X Notice of Draftsperson's Patent Drawing Review, PTO-948
3 X [illegible]
4 Interview Summary, PTO-413, Paper No.s
5 Notice of Informal Patent Application, PTO-152

DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 8/12/02 is acknowledged. Applicant elected, with traverse, Group I, claims 1-4, 9-11, 15,16,18-21 to the extent it addresses polynucleotides encoding polypeptide SEQ ID No. 2. Applicant argues that Groups I-V, XVI, XVII should be rejoined as there is no additional burden in searching them together. Upon further consideration of the terminology used in the application, Examiner agrees to rejoin Group I with claims 7,8 of Group II, as claims drawn to polynucleotides encoding same full-length protein. As for the other Groups, the scope of the genuses encompassed by these Groups are different as they are drawn to polynucleotides encoding "mature" protein (claims 5,6 of Group II), polynucleotides encoding proteins which are >80% identical to proteins addressed in claim 1 (Group III), polynucleotides having 80% similarity to various fragments of proteins addressed in claim 1 (Groups XVI, XVII). Consequently, a reference teaching polynucleotide of, e.g. Group III or XVII, will not necessarily teach or suggest the product of Group I. The modified restriction requirement is still deemed proper and is therefore made FINAL. Claims 5,6,12-14,22-95 are withdrawn from further consideration by the

claims 5,6,12-14,17,22-95, and amendment of claims 1-4,7-11,15,16,18-21 to read

on elected invention (polynucleotides encoding polypeptide SEQ ID No. 2) are requested.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement filed 7/12/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. No copies of references of this "jumbo" IDS have been allocated. The IDS has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. The substitute specification filed 8/6/01 has not been entered because it does not conform to 37 CFR 1.125(b) because a marked-up copy of the substitute specification has not been supplied (in addition to the clean copy).

Claim Rejections - 35 USC § 112, second paragraph

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1,4,9-11,15,16,18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "about" in claims 1,2,4, 9,10 is a relative term which renders the claims indefinite.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1,7,15,16,18-21are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time

The claims are drawn to polynucleotides having at least 80% degree of identity with polynucleotides encoding protein of SEQ ID Nos. 2 (which is a protein addressed as PRO10282 or Stra6). As described in the specification, the polynucleotide SEQ ID No. 1 (which encodes protein SEQ ID No. 2) is overexpressed in cancer tissues and thus can be used for cancer diagnostics. Polynucleotide SEQ ID No. 1 itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims as drawn to nucleotide sequences having more than 80% identity to said polynucleotide do not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less then 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be useful in the detection of cancer are present in the specification. Therefore, sequence similarity result in an

sequence and a similar biomolecule of known function or expression. With the

exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. Accordingly, the specification does not provide a written description of the polynucleotide as claimed, and, consequently, of their complement. Note, that even though specification indicates that SEQ ID Nos. 2,5 contain open reading frame encoding protein SEQ ID NO:2 or 5, the claims are not drawn to polynucleotides encoding a particular protein. The specification provides insufficient written description to support the genus encompassed by the claim.

6. Claims 1,7,9,15,16,18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotide encoding peptide SEQ ID No. 2 (i.e., protein addressed as PRO10282 or Stra6), does not reasonably

the specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As described in the specification, the polynucleotide SEQ ID No. 1 (which encodes protein SEQ ID No. 2) is over-expressed in cancer tissues and thus can be used for cancer diagnostics. No information about overexpression of any other polynucleotides, e.g., polynucleotides having certain % identity, or certain degree of hybridization to the polynucleotide SEQ ID No. 1 is present in the specification. Specification notes that Stra6 proteins "may function as receptors for an unknown ligand" (paragraph bridging pages 2 and 3), but no specific guidance in this regard is present. Prior art does not guide how to use Stra6 peptides other than natural murine protein PRO10282. Therefore, in view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not use the invention with the claimed breadth without an undue amount of experimentation.

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1,7, 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by the sequence of Database GenEmbl, accession number AF062476. The referenced sequence shows 82.3% similarity to nucleic acid encoding residues 1-667 of protein SEQ ID No. 2 of the instant invention (see attached sequence alignment). Therefore, the referenced polynucleotide reads on the polynucleotide of claim 1 which has ≥80% similarity to nucleic acid encoding residues 1-667 of protein SEQ ID No. 2. Further, as the referenced sequence has continuous stretches matching the claimed polynucleotide, it will hybridize to nucleic acid encoding residues 1-667 of protein SEQ ID No. 2, in particular under high stringency conditions (absent evidence to the contrary). Consequently, the referenced sequence also reads on the product of claims 9-11.

8. Claims 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by the sequence of Database GenEmbl, accession number AAV84436. The referenced sequence shows 92% local similarity to a fragment of nucleic acid SEQ ID No. 1 (i.e, nucleic acid encoding residues 1-667 of protein SEQ ID No. 2; see attached sequence

the claimed polynucleotide, and it will hybridize to nucleic acid encoding residues 1-

667 of protein SEQ ID No. 2, in particular under high stringency conditions (absent evidence to the contrary).

Conclusion.

9. No claims are allowed.

10. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mlb